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Gaétan Prince
Direct Dial: (514) 397-6725
gp@bcf.ca

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Commissioner of Patents
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Box PCT
Ottawa/Hull K1A 0C9

Re : International Application No. PCT/CA2005/000217
Filed on February 18th 2005
Title : METHOD AND DEVICE USING MYOELECTRICAL ACTIVITY FOR OPTIMIZING A
PATIENT'S VENTILATORY ASSIST
Applicant : MAQUET CRITICAL CARE AB et al.
Our file : 08831-012

Dear Sirs:

This is in response to the International Search Report mailed on July 4th, 2005, and to the Written Opinion accompanying this International Search Report.

In this Written Opinion, the Examiner cites documents D1 (EP 1 366 779 A1) and D2 (WO 02/056818 A2) and states that none of the 18 claims presently on file meet the criteria of Article 33(3) PCT.

Enclosed herewith is a new set of claims, to be substituted to the original set of claims, in which independent claim 1 and independent claim 10 have been amended to better define the invention.

More specifically, the preamble of independent claim 1 has been amended to recite "A method for determining a level of ventilatory assist to a ventilator-dependent patient for reducing the risk of respiratory muscle fatigue, the method comprising: ..." (emphasis added).

Similarly, the preamble of independent claim 10 has been amended to recite "A device for determining a level of ventilatory assist to a ventilator-dependent patient for reducing the risk of respiratory muscle fatigue, the device comprising: ..." (emphasis added).

BCF LLP

Montréal
1100 René-Lévesque Blvd. West, 25th Floor, Montréal, Québec H3B 5C9
Telephone: (514) 397-8500 Fax: (514) 397-8515 www.bcf.ca

Québec
800 Place d'Youville, 19th Floor, Québec, Québec G1R 3P4
Telephone: (418) 266-4500 Fax: (418) 266-4515 www.bcf.ca

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As can be seen, we have amended the preamble of claims 1 and 10 to indicate that the present invention is concerned with a method and a device that reduce the risk of respiratory muscle fatigue.

The cited prior art D1 and D2 are not concerned with the reduction of the risk of respiratory muscle fatigue. Accordingly, neither D1 nor D2 specify a respiratory muscle fatigue critical threshold nor the control of the level of ventilatory assist in relation to this critical threshold.

Indeed, D1 is mainly concerned with the comparison of the level of the EMG intensity with a given limit (see paragraph 56). This document is silent as to the determination of this given limit. It appears that the given limit value is predetermined and not calculated.

As indicated in the abstract of document D2, this document is concerned with the detection of airway leaks between the ventilator and the patient. More specifically, the amplitude of the myoelectrical signal is compared to a given threshold, and airway leaks are sealed when the amplitude of the myoelectrical signal is higher than this threshold.

Page 26, last paragraph, of document D2 explains that the determination of the level to be exceeded (threshold) in terms of amplitude and duration can either be performed by manual adjustment supervised via visual feedback, or by automatically letting the level be relative to the mean noise level. Obviously, this threshold is not related to respiration muscle fatigue in any manner.

In view of the above amendments and remarks, reconsideration of the present patent application is requested.

Yours very truly,

BKP GP (formerly BROUILLETTE KOSIE PRINCE)

A handwritten signature in black ink, appearing to be 'Gaétan Prince', written over a horizontal line.

Gaétan Prince

GP/MJ/ML/
Encls.

WHAT IS CLAIMED IS:

1. A method for determining a level of ventilatory assist to a ventilator-dependent patient for reducing the risk of respiratory muscle fatigue, the method
5 comprising:

calculating a respiratory muscle fatigue critical threshold of a respiration-related feature, wherein fatigue of a respiratory muscle of the ventilator-dependent patient develops when the critical threshold is reached by the respiration-related feature; and

controlling the level of ventilatory assist to the ventilator-dependent patient in
10 relation to the critical threshold of the respiration-related feature so as to prevent fatigue of the patient's respiratory muscle.

2. A method for determining a level of ventilatory assist as defined in claim 1, wherein:

15 calculating a critical threshold of the respiration-related feature comprises calculating a critical signal strength of an electrical activity of the patient's respiratory muscle above which muscle fatigue develops; and

controlling the level of ventilatory assist comprises preventing the signal strength of the electrical activity of the patient's respiratory muscle to exceed the critical
20 signal strength to prevent fatigue of the respiratory muscle.

3. A method for determining a level of ventilatory assist as defined in claim 2, wherein calculating a critical signal strength of the electrical activity of the patient's respiratory muscle comprises:

25 calculating a critical value of a relative spectral change of the electrical activity of the patient's respiratory muscle above which long term fatigue of the respiratory muscle develops; and

using the critical value of the relative spectral change to calculate the critical signal strength of the electrical activity of the patient's respiratory muscle.

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4. A method for determining a level of ventilatory assist as defined in claim 2, wherein calculating a critical signal strength of the electrical activity of the patient's respiratory muscle comprises:

determining a critical respiratory muscle force level above which muscle fatigue starts to develop; and

in response to the critical respiratory muscle force level, calculating a critical signal strength of the electrical activity of the patient's respiratory muscle under which
5 isometric fatigue of the respiratory muscle does not develop.

5. A method for determining a level of ventilatory assist as defined in claim 1, wherein:

calculating a critical threshold of the respiration-related feature comprises
10 calculating a critical level of a transdiaphragmatic pressure of the ventilator-dependent patient above which muscle fatigue develops; and

controlling the level of ventilatory assist comprises preventing the patient's transdiaphragmatic pressure to exceed the critical level of the transdiaphragmatic pressure to prevent fatigue of the respiratory muscle.

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6. A method for determining a level of ventilatory assist as defined in claim 5, wherein calculating a critical level of the transdiaphragmatic pressure comprises:

calculating a critical value of a relative spectral change of the electrical activity of the patient's respiratory muscle above which long term fatigue of the respiratory
20 muscle develops;

calculating a respiratory duty cycle; and

using the critical value of the relative spectral change and the respiratory duty cycle to calculate the critical level of the transdiaphragmatic pressure.

25 7. A method for determining a level of ventilatory assist as defined in claim 1, wherein calculating a critical threshold of the respiration-related feature comprises:

calculating a first critical signal strength of an electrical activity of the patient's respiratory muscle above which muscle fatigue develops; and

determining a critical muscle force level above which muscle fatigue develops
30 and, in response to the critical muscle force level, calculating a second critical signal strength of the electrical activity of the respiratory muscle under which isometric fatigue of the respiratory muscle does not develop; and

wherein controlling the level of ventilatory assist comprises preventing the signal strength of the electrical activity of the respiratory muscle to exceed either the first and second critical signal strengths to prevent fatigue of the respiratory muscle.

5 8. A method for determining a level of ventilatory assist as defined in claim 1, wherein calculating a critical threshold of the respiration-related feature comprises:
 calculating a critical level of a transdiaphragmatic pressure above which muscle fatigue develops; and

 calculating a critical signal strength of an electrical activity of the patient's
10 respiratory muscle above which muscle fatigue develops; and
 wherein controlling the level of ventilatory assist comprises:

 preventing the transdiaphragmatic pressure to exceed the critical level of the transdiaphragmatic pressure to prevent fatigue of the patient's respiratory muscle; and
 preventing the signal strength of the electrical activity of the patient's respiratory
15 muscle to exceed the critical signal strength to prevent fatigue of the patient's respiratory muscle.

 9. A method for determining a level of ventilatory assist as defined in claim 1, wherein the patient's respiratory muscle comprises the patient's diaphragm.
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 10. A device for determining a level of ventilatory assist to a ventilator-dependent patient for reducing the risk of respiratory muscle fatigue, the device comprising:

 a calculator of a critical threshold of a respiration-related feature, wherein
25 fatigue of a respiratory muscle of the ventilator-dependent patient develops when the critical threshold is reached by the respiration-related feature; and

 a controller of the level of ventilatory assist to the ventilator-dependent patient in relation to the critical threshold of the respiration-related feature so as to prevent fatigue of the patient's respiratory muscle.
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 11. A device for determining a level of ventilatory assist as defined in claim 10, wherein:

the calculator computes a critical signal strength of an electrical activity of the patient's respiratory muscle above which muscle fatigue develops;

the device comprises a detector of the signal strength of the electrical activity of the respiratory muscle; and

- 5 the controller prevents the signal strength of the electrical activity of the patient's respiratory muscle to exceed the critical signal strength to prevent fatigue of the patient's respiratory muscle.

12. A device for determining a level of ventilatory assist as defined in claim 11,
10 wherein the calculator:

calculates a critical value of a relative spectral change of the electrical activity of the patient's respiratory muscle above which long term fatigue of the respiratory muscle develops; and

- 15 uses the critical value of the relative spectral change to calculate the critical signal strength of the electrical activity of the patient's respiratory muscle.

13. A device for determining a level of ventilatory assist as defined in claim 11,
wherein the calculator:

- 20 determines a critical respiratory muscle force level above which muscle fatigue starts to develop; and

in response to the critical respiratory muscle force level, calculates a critical signal strength of the electrical activity of the patient's respiratory muscle under which isometric fatigue of the respiratory muscle does not develop.

- 25 14. A device for determining a level of ventilatory assist as defined in claim 10, wherein:

the calculator computes a critical level of a transdiaphragmatic pressure of the ventilator-dependent patient above which muscle fatigue develops;

- 30 the device comprises a detector of the patient's transdiaphragmatic pressure; and

the controller prevents the patient's transdiaphragmatic pressure to exceed the critical level of the transdiaphragmatic pressure to prevent fatigue of the patient's respiratory muscle.

15. A device for determining a level of ventilatory assist as defined in claim 14, wherein the calculator:

calculates a critical value of a relative spectral change of the electrical activity of the patient's respiratory muscle above which long term fatigue of the patient's respiratory muscle develops;

calculates a respiratory duty cycle; and

uses the critical value of the relative spectral change and the respiratory duty cycle to calculate the critical level of the patient's transdiaphragmatic pressure.

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16. A device for determining a level of ventilatory assist as defined in claim 10, wherein:

the calculator (a) calculates a first critical signal strength of an electrical activity of the patient's respiratory muscle above which muscle fatigue develops, and (b) determines a critical muscle force level above which muscle fatigue starts to develop and, in response to the critical muscle force level, calculates a second critical signal strength of the electrical activity of the patient's respiratory muscle under which isometric fatigue of the respiratory muscle does not develop;

the device comprises a detector of the signal strength of the electrical activity of the patient's respiratory muscle; and

the controller prevents the signal strength of the electrical activity of the patient's respiratory muscle to exceed either the first and second critical signal strengths to prevent fatigue of the patient's respiratory muscle.

17. A device for determining a level of ventilatory assist as defined in claim 10, wherein:

the calculator (a) calculates a critical level of a transdiaphragmatic pressure above which muscle fatigue develops, and (b) calculates a critical signal strength of an electrical activity of the patient's respiratory muscle above which muscle fatigue develops;

the device comprises a detector of the patient's transdiaphragmatic pressure, and a detector of the signal strength of the electrical activity of the patient's respiratory muscle; and

the controller (a) prevents the transdiaphragmatic pressure to exceed the critical level of the transdiaphragmatic pressure to prevent fatigue of the respiratory muscle, and prevents the signal strength of the electrical activity of the patient's respiratory muscle to exceed the critical signal strength to prevent fatigue of the patient's respiratory muscle.

18. A device for determining a level of ventilatory assist as defined in claim 10, wherein the patient's respiratory muscle comprises the patient's diaphragm.